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(71)(72) Applicant and Inventor: FARRELL, Edward, M. [US/CA]; 66 Dolan Drive, Nepean, Ontario K2J 1Z1 (CA).

(74) Agent: CREEDON, Vincent, M.; Wenderoth, Lind & Ponack, Southern Building, Suite 700, 805 Fifteenth Street, N.W., Washington, DC 20005 (US).

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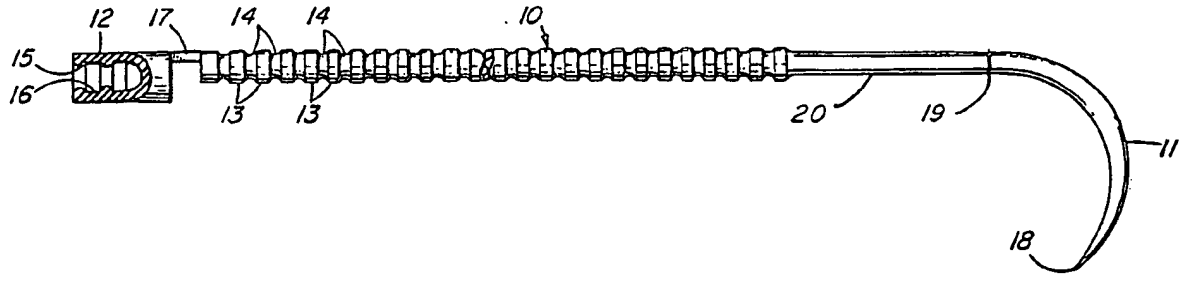

(57) Abstract

A sternal tie for post-surgical reconnection of the severed halves of a sternum. The tie comprises an elongated body with needle (11) means at one end and a sleeve (12) at the opposite end, the exterior of the body having a series of lands (13) and grooves (14) adapted to mate with the lands (15) and grooves (16) provided on the inside of the sleeve (12). The tie is preferably formed from a biodegradable plastic material and is adapted for tightening by a suitable tool. The tie is less irritating to the patient than known techniques for joining the sternum after surgery.

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SURGICAL TYING DEVICES

This invention relates to fastening devices, and especially to devices for use in closing a severed sternum following thoracic surgery.

In cardiovascular and thoracic surgery, particularly open heart surgery, it is conventional practice to sever the sternum longitudinally and then to retract the severed sternum, and the ribs, to allow access to the internal organs, such as the heart.

The joining of the severed halves of the sternum following surgery presents a problem. A known procedure is to use suture wires, the suture wires being threaded through tissue on each side of the severed sternum through a portion of the cartilage of the sternum located between the ribs. The ends of the wire are twisted together and snipped above the twist.

The technique disclosed above suffers from a number of disadvantages. Not the least among these is that it is very hard for the surgeon to select the appropriate tension on the suture wire to hold the sternum together. Further, the severed ends of the wires can result in macerative damage to the cartilage or the thin layer of tissue above the sternum and can even cut into the sternum. The strength of such sutures is also of critical importance, because quite frequently following chest surgery the patient has a need to cough. Coughing creates considerable strain in the rib structure, and tends to disturb the integrity of sutures applied in the above manner. Still further, the severed ends of the wire irritate the patient

and indeed can cause infection in some cases. The wire can damage bone and surrounding tissue which of course is also highly undesirable, and sets up a fracture site.

A number of attempts have been made to solve the above problems. For example, in United States Patent No. 4,201,215 of May 6, 1980 there is disclosed a sternal clamp comprising a metal band that is crimped into position. However, the clamp disclosed in the patent involves burning of opposed and matching holes through each side of the severed cartilage of the sternum and inserting hooks through the holes, then tightening the engagement between the clamping members so that the severed sides of the cartilage are positioned to close the opening. The latter step, and the crimping step necessary to secure the clamp, involve the use of tools and it will be self evident that tissue has to be damaged. The clamp is hard to remove. Further, the teachings of the United States patent do not dispose of the requirement for separate sutures.

Other attempts have been made to solve problems like those defined above. These include the provision of fastening devices formed from plastics and having integral hook-like needles intended to assist in penetrating tissue. Such a construction is illustrated in United States Patent No. 3,570,497 of March 16, 1971. While the structure illustrated in this patent is primarily intended for conventional suturing, it might otherwise be considered suitable for a sternal clamp, however, it has the disadvantage that once in place the structure necessary for locking the suture into a loop is of a size such as to create a protrusion, resting on top of the sternum, that would be irritating to the patient. A further disadvantage of other known sternal closure structures is that they are usually formed of materials, such as stainless steel, that may have to be removed; such removal can be difficult. There accordingly exists a requirement for a sternal clamp or tie that will satisfy the following needs:

1. It can readily be inserted through the tissue

surrounding the sternum minimizing risk of damaging internal organs;

2. Control of the amount of tension placed on the article during the closing of the incision can be precise;

3. There must be no substantial projection of the article into the tissue over the sternum;

4. It is desirable for the article to be formed from a biodegradable plastic.

5. It must have considerable strength.

In its broadest aspect, therefore, the present invention provides a sternal tie comprising: (i) an elongated body having a first end and a second end; (ii) needle means at the first end for perforating tissue adjacent the sternum; (iii) a central portion of the body being formed with a series of alternating lands and grooves; (iv) a sleeve integral with the second end of the body; (v) the sleeve having an inside surface formed with a plurality of alternating lands and grooves matching in shape the lands and grooves on the body; (vi) the sleeve having a length greater than its thickness; (vii) at least the sleeve and the body being formed from a suitable plastic material; whereby the body may be placed around the two halves of a sternum, the needle and the first end threaded through the sleeve so that the lands and grooves on the body engage the lands and grooves in the sleeve, and the threading action continued until the two halves of the sternum are tightly brought together and secured in position, the sleeve deforming resiliently outward.

In the attached drawings, which illustrate embodiments of the invention:

Figure 1 is a side view of a fastening device prior to use;

Figure 2 is an illustration of a portion of the device of Figure 1, with the connection completed;

Figure 3 is an illustration of the device of Figure 1 about to be placed in position about the sternum

following surgery;

Figure 4 illustrates the device after mating of the male and female portions and after removal of the needle; and

Figures 5 and 6 are illustrations of alternative forms of the fastener.

Referring first to Figure 1, the main body 10 of the fastener or tie has an exterior surface comprising a series of alternating lands 13 and grooves 14. The body 10 has a relatively thin cylindrical portion 20, to which there is connected, at end 19, by conventional means, e.g. swaging, a curved needle 11 having a point 18.

Integral with the body 10 of the connector, and joined thereto to by a connecting element 17, is a sleeve 12 having an interior surface comprising lands 15 and grooves 16 that mate with the grooves 14 and the lands 13 of the body 10. It is desirable but not necessary that the lands and grooves merge into each other smoothly to avoid damage to the tissue as the clamp is passed around the sternum.

In Figure 3, an article according to the invention is shown just after the needle 11 has been passed around the sternum halves 22, 22' to form a loop resulting in the sleeve 12 and the needle 11 being more or less aligned anterior to the sternum. The needle 11 is then passed through the sleeve 12, and it can readily be understood that the narrow portion 20 of the element 10 can be passed without interference through the sleeve 12. Then, a conventional clamping tool is used to grip portion 20 and forceably draw it through the sleeve 12; the resistance created by the lands and grooves in both of the elements is overcome by the tool, of a type known in the art, and precise regulation of the amount of tension applied to the portion 20 can be achieved by the tool to achieve a carefully measured tightness of the element 10 around the severed halves of the sternum 22, 22'.

It can readily be seen that when in place, the

article according to the invention lies relatively flat against the sternum. Further, if the article is manufactured from a biodegradable material, after a predetermined length of time, established by the nature of the biodegradable material, the fastener will disintegrate after the sternum has healed.

In the embodiment of Figure 6, instead of the female element being attached to the end of the main body it is beside the end of the main body. This form of the invention ensures that the article lies flat against the anterior surface of the sternum thus reducing irritation to the patient. The embodiment of Figure 6 also disposes of the problem of selection of the dimensions of element 17 of Figure 1 if a biodegradable material is used.

It will be apparent to those skilled in the art that variations can be made in the shape of the exterior of the portion 10 and thus of the interior of the female portion 12 so long as the frictional engagement between the two parts is sufficient to prevent unwanted separation. Such a variant is shown in Figure 5, in which the lands and grooves have the form of a series of frusto-conical sections.

Turning now to the formation of the sleeve, the configuration of the interior of the sleeve, namely the lands and grooves 15 and 16, can be formed with a retractable tool as is known in the art. Alternatively, the sleeve may be formed in two halves, which are later joined together to form a unitary sleeve. A third possibility, perhaps desirable with certain forms of plastic materials, is to form the lands and grooves on the interior of a very thin sleeve slit axially, the axial slit being closed by the later placement of a sleeve of resilient material surrounding the first formed portion. Still further, a soluble core can be used and dissolved after the tie is formed.

Suitable biodegradable plastic materials include polyorthoester, polyglyconate and its copolymers, and

polydioxanone and its copolymers. Nonbiodegradable plastics such as polyethylene terephthalate, polybutylene and its copolymers, and isotactic polypropylene can be used. Other suitable materials will be known to those skilled in the art and the specific nature of the materials can be selected according to the specific requirements for the fastener. Since the materials used do not form part of this invention a detailed discussion of the materials is not believed necessary.

It will readily be seen that the invention provides a fastener having a low outside diameter that makes it highly suitable for use in surgical applications. Discomfort to the patient is minimized, and the work of the surgeon substantially reduced.

CLAIMS:

1. A fastener device for joining the reversed halves of a sternum, comprising:

(i) an elongated body having a first end and a second end;

(ii) needle means at the first end for perforating tissue adjacent the sternum;

(iii) a central portion of the body being formed with a series of alternating lands and grooves;

(iv) a sleeve integral with the second end of the body;

(v) the sleeve having an inside surface formed with a plurality of alternating lands and grooves matching in shape the lands and grooves on the body;

(vi) the sleeve having a length greater than its thickness;

(vii) at least the sleeve and the body being formed from a suitable plastic material;

whereby the body may be placed around the sternum, the needle and the first end threaded through the sleeve so that the lands and grooves on the body engage the lands and grooves in the sleeve, and the threading action continued until the two halves of the sternum are tightly brought together and secured in position, the sleeve deforming resiliently outward.

2. The device defined in claim 1 wherein the needle is formed from metal, is curved, and is secured to the first end of the body.

3. The device defined in one of claims 1 or 2 wherein the sleeve is coaxial with the body.

4. The device defined in one of claims 1-3 wherein the axis of the sleeve is parallel to the axis of the body.

5. The device defined in one of claims 1-4 wherein there is provided, between the needle means and the lands and grooves on the body, a cylindrical section longer than the sleeve and having an outside diameter no greater than the inside diameter of the grooves on the body.

6. The device defined in one of claims 1-5 wherein the lands and grooves both in the sleeve and on the body define a series of frusto-conical portions tapering inwardly toward the first end.

7. The device defined in one of claims 1-6 wherein the plastic material is a biodegradable material.

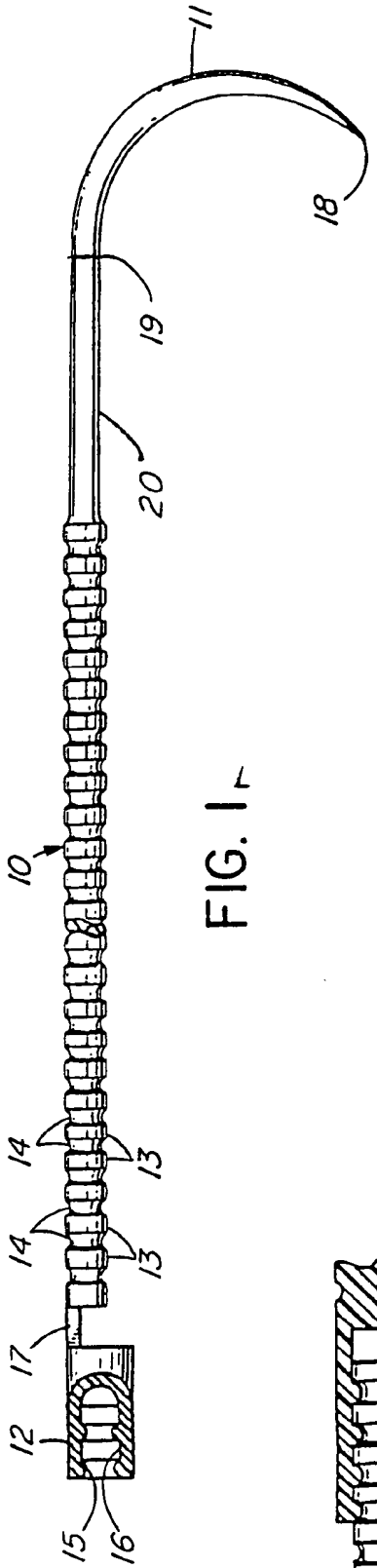

FIG. 1

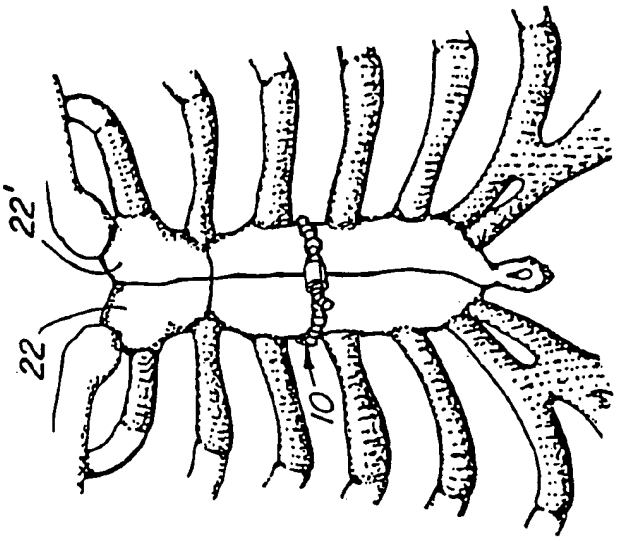

FIG. 4

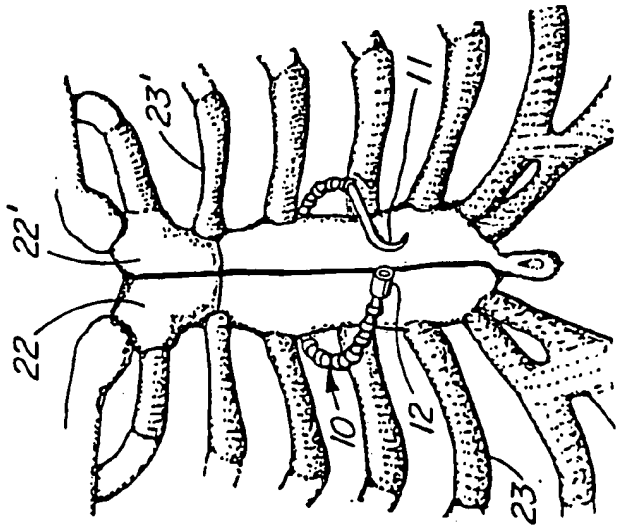

FIG. 3

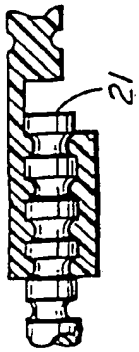

FIG. 2

FIG. 5

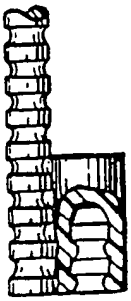

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 88/00477

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [8]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 17/56

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	FR, A, 2357229 (PARTRIDGE) 3 February 1978, see the whole document	1
Y		2,3,4,6,7
A		5
Y	US, A, 3570497 (LEMOLE) 16 March 1971, see abstract; figures (cited in the application)	2,3,4,6
Y	US, A, 2987062 (ELLISON) 6 June 1961, see claim 2; figures	7
A	US, A, 3971384 (HASSON) 27 July 1976	
A	US, A, 4201215 (CROSSETT) 6 May 1980 (cited in the application)	
P,A	EP, A, 0238219 (SUTHERLAND) 23 September 1987, see abstract; figures; column 3, line 5 - column 4, line 27	1

* Special categories of cited documents: [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
17th June 1988	15 JUIL. 1988
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 8800477 SA 21954

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 04/07/88
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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US-A- 3570497	16-03-71	None		
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